

**REMARKS**

Applicants appreciate the Examiner's consideration and entering into record of the amendments submitted on March 23, 2007, which include the amendments to the specification, claims and drawing (Figure 5).

Claims 47-107 were previously submitted for examination. Claims 47-68 and 98-107 were withdrawn from consideration. Claims 1-46 were canceled by the Preliminary Amendment submitted on January 16, 2004 and claims 72-77, 85, 87-91 and 94 were canceled by the March 23, 2007 Amendment. Claims 69, 78 and 92 have been amended by the present Amendment. Therefore claims 69-71, 78-84, 86, 92, 93 and 95-97 are under active consideration.

Accordingly, the present amendments do not introduce any new matter. Entry of the amendments is respectfully requested.

With respect to all amendments and canceled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

**Withdrawn rejections**

Applicants appreciate the Examiner's withdraw of the following rejections raised in the October 23, 2006 Office Action:

- the anticipation rejections over Fischer, Magerlein (I), Magerlein (II) and Colford, respectively;
- the obviousness rejection over Magerlein (I), Magerlein (II) or Colford in view of Gotschlich; and

- the obviousness rejection over Magerlein (I), Magerlein (II) or Colford in view of Chang.

### **Objection to the specification**

The specification is objected to as allegedly failing to provide proper antecedent basis for the claimed subject matter. According to the Examiner:

The instant claims recites [sic] an antibody [that] recognizes a bioactive, three-dimensional epitope of a parathyroid hormone PTH. However, no disclosure of any bioactive, three-dimensional epitope [sic] is found in the specification.

Applicants submit that the underlying issue for this objection is the same as the lack of written description/new matter rejection under 35 U.S.C. 112 raised in the same Office Action. Accordingly, please see the applicants' response to the lack of written description/new matter rejection as discussed below.

### **Double-Patenting Rejection**

Claims 69-71, 78-84, 92, 93 and 95-97 are rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-3, 20, 22, 38, 46 and 48 of Reexam No. 90007732 (U.S. patent No. 6,689,566).

This rejection is obviated by the Terminal Disclaimer submitted herewith.

In view of the foregoing, applicants respectfully request reconsideration and withdrawal of the double patenting rejection of claims 69-71, 78-84, 92, 93 and 95-97 over U.S. patent No. 6,689,566.

**Rejection under 35 U.S.C. § 112, first paragraph - New matter**

Claims 69, 71, 78-84, 86, 92, 93 and 95-97 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleged that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

"three-dimensional epitope within a PTH fragment"

According to the Examiner:

It is noted that the instant claim recites "an antibody binds to a bioactive, three-dimensional epitope of a parathyroid hormone (PTH), wherein said isolated antibody binds to said three-dimensional epitope within a whole PTH with a higher affinity than its binding to said three-dimensional epitope within a PTH fragment". No support from the specification can be found. Although applicant in the Remarks indicates the inherent characteristics of the antibody, particularly at page 8, line 24-25 and Figure 11, however no "three-dimensional" epitope PTH fragment was never [sic] discussed in the whole specification (See Remarks page 13, fourth paragraph). Furthermore, applicant also submitted Dr. Lerner's binding analysis in support of the assertion with respect to the newly amended claims. Surap (See Exhibit B). Examiner acknowledges the experimental data provided by Dr. Lerner as "inherent" properties of the instant antibody. Nonetheless, the newly amended claims lack support from the original specification, particularly with the term "three-dimensional epitope"

PTH fragment. It is a new matter. The application belongs to "Continuation-in-Part", not "Continuation" from its parent case (US PAT 6,743,590). (emphasis added.)

Applicants respectfully traverse this rejection. There is no doubt that an exemplary antibody encompassed by the presently pending claims is disclosed in the present application and the parent Application No. 09/344,639. (*See e.g.*, Figure 11 of the present application and the parent Application No. 09/344,639, which was submitted as Exhibit C of the Preliminary Amendment submitted on January 16, 2004.) In addition, the Examiner acknowledged the experimental data provided by Dr. Lerner as "inherent" properties of the exemplary antibody.

As discussed in the March 23, 2007 Amendment, because the conformational or the three-dimensional epitopes are formed from two or more stretches of polypeptide that are distant from one another in the primary structure, this means that the conformational or the three-dimensional epitopes are better formed when the entire protein is at its natural conformation. This also means that perturbing the natural conformation of the entire protein, *e.g.*, making a fragment from the entire protein containing the conformational or the three-dimensional epitopes, may very well perturb the conformational or the three-dimensional epitopes situated in a non-natural environment. It follows that if an antibody binds to a three-dimensional epitope, the antibody should bind to the entire protein, which contains the three-dimensional epitope in its natural environment, better than binding to the same three-dimensional epitope in a fragment of the protein.

Also as discussed in the March 23, 2007 Amendment, the testing data described in the Lerner Report indicate that the exemplary antibody, the labeled antibody of Scantibodies' whole PTH tests, binds to a three-dimensional epitope within the whole PTH molecule because the antibody binds to the epitope within the whole PTH molecule better than binding to the epitope in a short PTH peptide.

It is a well established principle that by disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says

nothing explicit concerning it. MPEP § 2163.07(a) (emphasis added). The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *Id* (emphasis added).

In the present case, an exemplary antibody encompassed by the presently pending claims is disclosed in the present application and the parent Application No. 09/344,639. The Examiner also acknowledged that the experimental data provided by Dr. Lerner are “inherent” properties of the exemplary antibody, which indicate that the exemplary antibody binds to a three-dimensional epitope within a whole PTH with a higher affinity than its binding to the three-dimensional epitope within a PTH fragment. As such, the recitation of the “inherent” properties of the exemplary antibody in the presently pending claims does not introduce any new matter, and the present application and the parent Application No. 09/344,639 provide adequate written description for the presently pending claims, albeit inherently by disclosing the exemplary antibody.

In view of the foregoing, applicants respectfully request reconsideration and withdrawal of this lack of written description/new matter rejection of the presently pending claims, and the objection to the present specification on the same ground.

non-(1-86) PTH fragment

According to the Examiner:

No support for the non-(1-86) PTH fragment is disclosed either from this application, or from its CIP US Patent 6689566. Applicant mentions in the Remarks that the support can be found at page 8, line 24-25 and Figure 11. However, the support from the above mentioned specification disclosing only non-(1-84) PTH fragment. Furthermore, the sequence data disclosed by applicant also show (1-84) PTH, not (1-86) PTH (See Sequence list).

This rejection is obviated by the amendments of claims 69, 78 and 92.

In view of the foregoing, applicants respectfully request reconsideration and withdrawal of this lack of written description/new matter rejection of the presently pending claims.

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, the applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 532212000624.

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